REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 5, 6, 20 and 22-24 are pending upon entry of the foregoing amendments. Claims 1 and 4 have been canceled without prejudice or disclaimer. The cancellation of claims made herein does not constitute acquiescence in the propriety of any objection or rejection made by the Examiner, but is made merely to advance the case towards allowance.

Claim 5 has been amended to be an independent claim in view of cancellation of claim 1 and to be directed to elected subject matter. Claim 5 further has been amended to recite the functional activity of the recited nucleic acid as a vaccine. Claims 6 and 20 have been amended to properly depend from claim 5 in view of cancellation of claim 4. Claim 22 has been amended to depend from claim 5, 6, or 20.

Applicants have added claims 23 and 24. Support for the new claims can be found throughout the specification, for example, on page 17, lines 9 14.

Applicants hereby submit formal drawings to substitute for the ones originally filed. The specification has been revised to incorporate the illustrations of the original Figures 14 and 15. No new matter has been introduced.

II. Rejection based on 35 U.S.C. § 1 12, second paragraph

The Examiner has rejected claims 1 and 4-6 as allegedly indefinite. Applicants respectfully traverse these rejections.

At the outset, Applicants note cancellation of claims 1 and 4, which renders moot the rejection of claims 1 and 4.

The Examiner has also rejected claim 5 alleging that recitation of "homologous" or "at least 80 % identity" is indefinite. Claim 5 has been revised not to recite "homologue". With respect to the recitation of "at least 80 % identity", the Examiner alleges that "there are no indications of the utilized algorithm to calculate the sequence identity". The Examiner further asserts that since "no art recognized convention exists regarding the calculation of percent identity, the claims are vague and indefinite".

It is well accepted that a claim should be read in view of the specification. Thus, a proper standard of determining the definiteness of claim language must consider the content of the particular application disclosure and the teachings of prior art.

Contrary to the Examiner's allegation, the specification of the instant application fully provides clear and ample disclosures of how to determine "percentage of sequence identity" (see page 12, line 20 to page 13, line 17). According to the specification, "percentage of sequence identity" is determined by comparing two "optimally aligned" sequences over a comparison window. Then, the specification describes algorithms that can be used for the optimal alignment (see page 12, last line to page 13, line 7). Furthermore, the specification explains how to calculate the percentage of identity, which does not need to use any algorithms. With the disclosure of algorithms combined with the sufficient descriptions of how to obtain percentage of sequence identity, one of ordinary skill in the art would easily understand the scope of claim 5 with a reasonable degree of particularity and certainty. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 5.

In view of the above amendment and the arguments, reconsideration and withdrawal of all the indefiniteness rejections are respectfully requested.

III. Rejection based on 35 U.S.C. § 172, first paragraph

Enablement Rejection

The Examiner has rejected claims 1, 4-6, 20 and 22 as allegedly non-enabled. The Examiner asserts that, while enabled for induction of antibody response utilizing SEQ ID NO: 25, the specification does not reasonably provide enablement for inducing a protective response as a vaccine. Applicants respectfully traverse this rejection.

The Examiner's rationale for the rejection seems to mainly rely on the finding that the specification does not show the induction of an immunogenic protective response against the claimed antigens or their fragments, which results in requiring undue experimentation for practicing the claimed invention. Contrary to the Examiner's understanding, however, a closer review of the specification reveals that the

specification sufficiently provides guidance as to how to make and use the claimed invention (page 44, line 28 page 48, line 3), as well as the actual test results (Example 8).

More specifically, in Example 8, four groups of 7 pigs received two injections of vaccine composition comprising a nucleic acid set forth in SEQ ID NO: 25 with a two-week interval, were challenged with PWD circovirus type B, and then evaluated by changes in growth and body temperature (hyperthermia). As shown in figures 14 and 15, the animals vaccinated with the claimed vaccine exhibit neither hyperthermia (except for a brief showing of hyperthermia during week 3), nor decrease in their growth, compared with control animals and/or animals without vaccination. Hyperthermia and weight loss are considered as clinical signs to determine the infection of PWD circovirus. That is, the test results in the specification clearly demonstrate that the claimed vaccine induces a protective response against infection of a PWD circovirus.

It is well settled that, during prosecution, the applicant's specification is deemed enabling in the absence of findings by the Examiner to the contrary. There is no doubt, therefore, that applicants enjoy a presumption of enablement, and that a failure by the PTO to rebut this presumption means that the present specification must be treated as enabling as a matter of law. Thus, it is the Examiner's burden to come forward with objective evidence to validate a doubt as to effects of the claimed invention as a vaccine. Applicants respectfully submit that the current action provides no such evidence.

As explained above, the specification provides credible evidence that the claimed invention acts as a vaccine by exhibiting a protective response against PWD circovirus. Therefore, given the test results, combined with a guidance provided by the specification as to how to practice the claimed vaccine, a person skilled in the art could practice the claimed invention as a vaccine without undue experimentation. Accordingly, applicants submit that the specification is enabled as a matter of law and in view of the experimental results detailed above, and thus respectfully request reconsideration and withdrawal of the enablement rejection.

Written Description Rejection

The Examiner has rejected claims 1, 4-6, 20 and 22 for alleged lack of written description for homologous sequences or fragments of the sequence set forth in SEQ ID NO: 25. Applicants respectfully traverse this rejection.

While not acquiescing to the propriety of the Examiner's position in the rejection, Applicants have obviated this rejection by amending the claims to omit recitation of fragments.

With respect to homologous sequences, Applicants note that claim 5 as amended specifies that the sequence identity is at least 80 % to the sequence set forth in SEQ ID NO: 25. The amended claim 5 further recites that the nucleotide sequence encodes an immunogenic protein that induces an effective protective response to infection by a PWD circovirus.

There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, and thus the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. See MPEP II. A. 2100 158. In this case, however, the Examiner has not met this burden.

As explained above, in addition to actual reduction to practice of a vaccine comprising a nucleic acid of SEQ ID NO: 25, the specification provides sufficient disclosures as to how to obtain nucleic sequences that have at least 80 % identity to that of SEQ ID NO: 25. Moreover, Applicants identified immunoreactive peptides of PWD circovirus type B, including peptides having amino acid sequences of SEQ ID Nos. 29, 30 and 32, that are present in the protein encoded by the nucleotide sequence of SEQ ID NO: 25. The identification of immunoreactive sites in the peptide encoded by SEQ ID NO: 25 further underscores that Applicants had invented not only the nucleotide sequence of SEQ ID NO: 25, but also nucleotide sequences having at least 80 % sequence identity to that of SEQ ID NO: 25 that encodes an immunogenic activity against PWD circovirus. Thus, the totality of the description clearly evidences that one of ordinary skill in the art would understand that applicants were in possession of the necessary common attributes possessed by the members of the

genus covered by at least 80 % identical variants of SEQ ID NO: 25. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Rejection of Claims 1, 4-6, 20 and 22 under 35 U.S.C. § 102 or § 103

The Examiner has rejected claims 1, 4-6, 20 and 22 as allegedly anticipated by or, as allegedly obvious over Meehan *et al.* ("Meehan"). Applicants respectfully traverse the rejection.

The Examiner asserts that Meehan discloses sequences that meet the limitations of the broad homologous limitation including 80 % homologous, and immunogenic fragments of the claimed invention. Alternatively, the Examiner contends that it would have been obvious to one of ordinary skill in the art to derive polypeptide from the disclosed sequence and utilize the fragments to enhance immune response.

At the outset, Applicants wish to draw the Examiner's attention to the amended claim 5 that specifies sequence identity as at least 80 %, and deletes recitation of sequence fragments. Meehan does not disclose nucleotide sequences having at least 80 % identity to the sequence of SEQ ID NO: 25.

Meehan identifies the complete nucleotide sequence of the genome of porcine circovirus (PCV) and suggests that PCV bridges the gap between animal and plant circoviruses. Meehan also discusses the taxonomic relationship of PCV with other members of the *Circoviridae*.

In particular, the PCV genome disclosed in Meehan corresponds to the sequence of the circovirus "circopormeeh" represented in figure 3 of the present specification or named "PCV PK/15" in the cited U.S. Patent No. 6,368,601 ("Allan 1" - see figure 5). As indicated in Allan 1, this circovirus PCV PK/15 that is the isolated circovirus disclosed in Meehan is a porcine circovirus type I (see column 1, lines 59-62), which, in turn, is named "type A" in the present application as filed.

The ORF13 of the PCV PK-15 disclosed in Allan 1 corresponds to the ORF2 of PCV type II or B (SEQ ID NO:25). As shown in Allan 1 in column 14, the second table and in Tables 3 and 4 of the present specification at page 60, the homology between the ORF13 sequence and the ORF2 sequences is only about 60%.

Furthermore, there is no disclosure or teaching of a pharmaceutical composition comprising the PCV genome and a pharmaceutically acceptable carrier, let alone a

vaccine. Therefore, Meehan discloses neither a nucleic acid comprising a nucleotide sequence with at least 80% identity to SEQ ID NO:25, nor the use thereof as a vaccine. Accordingly, Meehan fails to teach each and every element of the claimed invention and does not qualify as an anticipatory reference. In view of the above, Applicants respectfully request withdrawal of the anticipation rejection.

With respect to obviousness rejection, Meehan does not recognize any infectious diseases caused by the PCV genome, which would have led one of ordinary skill to formulate a pharmaceutical composition together with a pharmaceutically acceptable carrier, or to develop a vaccine. Furthermore, there is no disclosure in Meehan which may implicate or suggest the relation of PCV infection and PWD. In fact, Allan 1 confirmed that the PCV derived from the PK/15 cells, the sequence of which is reported in Meehan, is considered not to be pathogenic. Therefore, one of ordinary skill in the art would not have been motivated to obtain a vaccine as claimed from the teachings of Meehan that simply identifies the genome DNA of PCV. Thus, there is no *prima facie* case of obviousness. Accordingly, applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

V. Rejection of Claims 1 and 4/1, 4-5, 20 and 22 under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1 and 4 as allegedly anticipated by either U.S. Patent No. 6,368,601 ("Allan 1") or U.S. Patent No. 6,287,856 ("Poet"). The Examiner also has rejected claims 1, 4-5, 20 and 22 as allegedly anticipated by U.S. Patent No. 6,217,883 ("Allan 2"). Applicants respectfully traverse these rejections.

Applicants note that claims 1 and 4 have been cancelled, which renders moot the anticipation rejections based on Allan 1 or Poet. With respect to the Allan 2 reference, Applicants submit that the 35 U.S.C. § 102(e) date of Allan 2 is July 1, 1999 which is later than the filing date of the present application, December 4, 1998. More specifically, the U.S. application that matured to the Allan 2 patent claims priority to an application that was filed July 6, 1998 in France. Because the foreign priority date of the reference cannot be used to antedate the filing date of the application, the Allan 2 patent is only entitled to the 102(e) date when the application was filed in the U.S., which is July 1, 1999 (see MPEP 2136. 03, Section I, page 2100-92). As a

result, the Allan 2 patent does not qualify as an anticipatory reference against the instant application under § 102(e).

Accordingly, Applicants respectfully request reconsideration and withdrawal of all of the rejections under § 102(e).

In view of the foregoing, Applicants respectfully request reconsideration and allowance of the pending claims. If the Examiner has any questions concerning the foregoing, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date Jan. 13, 2003

By [signature] (28,665)

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VERSION WITH MARKINGS TO SHOW

CHANGES MADE – SPECIFICATION AND CLAIMS

Please delete a paragraph at page 9, lines 21-24, and substitute with the following paragraph:

Figure 14: Charts the results of experiments that demonstrate, in terms of percent hyperthermia, that vaccination with ORF'1 and ORF'2 of PCV-B enhances the level of protection in swine challenged with PCV-B (Percent hyperthermia: > 40.5°C, Control: not vaccinated and not challenged, ORF'1: vaccinated and challenged, ORF'2: vaccinated and challenged, ORF- :not vaccinated, challenged).

Please delete a paragraph at page 9, lines 26-28, and substitute with the following paragraph:

Figure 15: Charts the results of experiments that demonstrate, in terms of animal growth, that vaccination with ORF'1 and ORF'2 of PCV-B enhances the level of protection in swine challenged with PCV-B (Control: not vaccinated and not challenged, ORF'1: vaccinated and challenged, ORF'2: vaccinated and challenged, ORF- :not vaccinated, challenged).

In accordance with 37 C.F.R. § 1.121, please substitute for original claims 5, 6, 20 and 22, the following rewritten versions of the same claims, as amended. The changes are show explicitly in the attached "Version with Markings to Show Changes Made".

5. (Amended) A vaccine [according to claim 4] comprising a nucleic acid having a nucleotide sequence[, wherein the homologue has] with at least 80 % sequence identity to [SEQ ID No. 23 or] SEQ ID No. 25 and an acceptable pharmaceutical vehicle, wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease ("PWD") circovirus.

6. (Amended) A vaccine according to claim [4] 5, wherein [the] said nucleotide sequence is SEQ ID No. 25.

20. (Amended) A vaccine according to claim [4] 5, further comprising an adjuvant.

22. (Amended) A method of immunizing a mammal against piglet weight loss disease comprising administering to a mammal an effective amount of the vaccine of any one of claims [1-21] 5, 6 or 20.